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| APPLICATION NO.   | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO.                          | CONFIRMATION NO.                          |
|---|-------------|----------------------|--|---|
| 10/718,729  | 11/24/2003  | Toru Matsumoto       | Q78586                                       | 1837                                      |
| <div>23373      7590      07/05/2007</div> <div>SUGHRUE MION, PLLC</div> <div>2100 PENNSYLVANIA AVENUE, N.W.</div> <div>SUITE 800</div> <div>WASHINGTON, DC 20037</div> |             |                      |  |   |
|   |             |                      | <div>EXAMINER</div> <div>NAFF, DAVID M</div> |   |
|   |             |                      | <div>ART UNIT</div> <div>1657</div>          | <div>PAPER NUMBER</div>                   |
|   |             |                      | <div>MAIL DATE</div> <div>07/05/2007</div>   | <div>DELIVERY MODE</div> <div>PAPER</div> |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

|                              |                        |                     |  |
|------------------------------|------------------------|---------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b> | <b>Applicant(s)</b> |  |
|                              | 10/718,729             | MATSUMOTO, TORU     |  |
|                              | <b>Examiner</b>        | <b>Art Unit</b>     |  |
|                              | David M. Naff          | 1657                |  |

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 26 March 2007.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-39 is/are pending in the application.
- 4a) Of the above claim(s) 8-15, 24-27, 29-34, 36, 38 and 39 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-7, 16-23, 28, 35 and 37 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner:
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

**DETAILED ACTION**

An amendment of 3/26/07 amended claims 1, 3-5, 8, 11, 12, 13, 16, -21, 24, 25 and 28-33, and added new claims 35-39.

Claims in the application are 1-39.

5        Since new claims 36, 38 and 39 are dependent on non-elected withdrawn claims, these claims are included with the non-elected.

      Claims 8-15, 24-27, 29-34, 36, 38 and 39 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking  
10    claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 7/19/06.

      Claims examined on the merits are 1-7, 16-23, 28, 35 and 37.

      The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

15                    ***Claim Rejections - 35 USC § 112***

      The following is a quotation of the first paragraph of 35 U.S.C.

112:

20        The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

      Claims 1-7, 16-23, 28, 35 and 37 are rejected under 35  
25    U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the

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time the application was filed, had possession of the claimed invention.

Support is not found in the specification of the fluorine-containing polymer containing no other fluorine than the fluorines contained by the fluoroalkylene block as required in claims 1 and 16. This limitation is not recited in the specification, and basis in the specification for this limitation is not readily apparent.

Additionally, support is not found for "5% or less" in claims 35 and 37. The specification discloses only 5%.

10 ***Claim Rejections - 35 USC § 112***

Claims 35 and 37 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

15 The meaning of "mixtures diluted with pure water of alcohols or esters in a final concentration of 5% or less". Is the mixture a mixture of pure water and alcohols or esters? Additionally, it is unclear as to whether the mixture, pure water or alcohols and esters is 5% or less.

20 ***Claim Rejections - 35 USC § 103***

Claims 1-7, 28 and 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Matsumoto (EP 0 969 282 A2) in view of Mcaffrey et al (5,696,314) and Cozzette et al (5,200,051).

25 The claims are drawn to an enzyme electrode comprising an electrode on an insulating substrate, an immobilized enzyme layer on

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the electrode, an adhesion layer comprising a silane-containing compound over the immobilized enzyme layer, and a permeation-limiting layer comprising a fluorine-containing polymer having a pendent group containing a fluoroalkylene block attached to an unfluorinated vinyl-based polymer formed on the adhesion layer. The fluorine-containing polymer contains no other fluorine than the fluorines contained in the fluoroalkylene block.

Matsumoto discloses an enzyme electrode that is the same as presently claimed except the enzyme electrode of Matsumoto contains a binding layer (adhesion layer) between an electrode and immobilized enzyme layer instead of between the immobilized enzyme layer and the permeation-limiting layer as claimed. For example, see Figures 1 and 2, and description of the figures (page 13, line 15 to page 14, line 40).

McCaffrey et al disclose a multilayer enzyme electrode (Figure 1) that contains an adhesive layer that promotes adhesion between an immobilized enzyme layer and an enzyme/polymer layer, and between a dielectric layer and a microporous layer (col 7, lines 47-59).

Cozzette et al disclose a biosensor containing multiple layers. Adhesion between layers can be provided using a silane compound mixed with a solvent (col 26, section 5.1.2).

It would have been obvious provide an adhesion layer between the immobilized enzyme layer and the permeation-limiting layer of Matsumoto as suggested by McCaffrey et al using an adhesion layer to promote adhesion between a dielectric layer and a microporous layer,

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and between an immobilized enzyme layer and a enzyme/polymer layer, and Cozzette et al disclosing providing adhesion between multiple layers of a biosensor and using a reagent that provides adhesion between the layers. Having good adhesion between the immobilized enzyme layer and permeation-limiting layer of Matsumoto would have been expected to be advantageous, and using an adhesion layer would have been obvious in view of McCaffrey et al and Cozzette et al providing adhesion between layers of a multiple layer enzyme electrode and multiple layer biosensor by providing between layers a substance that promotes adhesion. It would have been obvious for the fluorine-containing polymer to contain no fluorine other than contained by the fluoroalkylene block since there would be no reasons to have fluorine present other than contained by the fluoroalkylene block. The conditions of dependent claims would have been obvious from conditions disclosed by Matsumoto, and if needed conditions disclosed by McCaffrey et al and Cozzette et al. Using a solution of silane-containing compound as to form the adhesion layer as in claim 35 would have been obvious since water is a readily available solvent.

#### ***Response to Arguments***

The remarks of the amendment urge that there is no motivation to provide an adhesion layer between the immobilized enzyme layer and the permeation-limiting layer of Matsumoto since the permeation-limiting layer is made of a polymer highly adhesive to the immobilized enzyme layer. However, Matsumoto does not teach that the permeation-limiting layer is highly adhesive to the immobilized enzyme layer. Using an

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adhesion layer as suggested by McCaffrey et al and Cozzette et al would have been obvious even if there is some adhesion between the permeation-limiting layer and the immobilized enzyme layer since the adhesion layer would have been expected to provide additional  
5 adhesion. In McCaffrey et al and Cozzette et al, there is adhesion between layers in the absence of the adhesion layer, but when using the adhesion layer there is stronger adhesion.

***Claim Rejections - 35 USC § 103***

Claims 16-23 and 37 are rejected under 35 U.S.C. 103(a) as being  
10 unpatentable over the references as applied to claims 1-7, 28 and 35 above, and further in view of Schillig et al (6,461,861 B2).

The claims require an enzyme electrode formed on an insulating substrate, an immobilized enzyme layer on the electrode, an adhesion layer on the immobilized enzyme layer and a permeation-limiting layer  
15 formed on the adhesion layer, wherein the permeation-limiting layer consists of a film comprising a fluorine-containing polymer having a pendent group containing a fluoroalkylene block attached to an unfluorinated vinyl-based polymer, and a plurality of grooves of a depth in the range of 0.1-100 nm built on the surface thereof. The  
20 fluorine-containing polymer contains no other fluorine than the fluorines contained in the fluoroalkylene block.

Matsumoto, McCaffrey et al and Cozzette et al are described above.

Schillig et al disclose a microbial membrane reactor for use in  
25 flow systems. The membrane may be fixed adjacent an electrode (col 1,

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line 47-48). Flow channels in the form of grooves (col 5, line 17) can be provided for flow of fluid over the surface of the membrane to provide substances metabolized by microorganisms contained by the membrane (col 2, lines 45-59 and col 3, lines 33-48).

5        When modifying Matsumoto to have an adhesion layer as set forth above, it would have been obvious to provide the permeation-limiting layer of Matsumoto with grooves as suggested by Schillig et al to provide channels for flow of fluid to the immobilized enzyme layer. Selecting a preferred depth of the grooves would have been within the  
10    skill of the art and obvious. In regard to claim 17, Cozzette et al disclose a multilayer biosensor, and suggest providing adhesion between layers by producing a rough topography between layers (col 26, lines 35-45). It would have been obvious to provide the surface of the permeation-limiting layer next to the immobilized enzyme layer  
15    with roughness as suggested by Cozzette et al provide better adhesion between the layers. The conditions of dependent claims would have been obvious from conditions disclosed by Matsumoto.

#### ***Response to Arguments***

20        The amendment urges that Schillig et al fails to suggest grooves on the outer surface of the permeation-limiting layer. However, the claims require the grooves on the surface rather than on the outer surface.

#### ***Double Patenting***

25        Claims 1-7, 16-23, 28, 35 and 37 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable



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over claims 1-53 of U.S. Patent No. 6,280,587 B1 in view of McCaffrey et al and Cozzette et al and Schillig et al..

It would been obvious to provide an adhesion layer between the immobilized enzyme layer and permeation-limiting layer of the enzyme electrode of the claims of the patent as suggested by McCaffrey et al and Cozzette et al for the type of reasons set forth above when applying these references to suggest an adhesion layer. Schillig et al would have suggested the permeation-limiting layer having grooves for reasons set forth above.

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#### ***Response to Arguments***

The amendment traverse this rejection based on reasons traversing the 103 rejection. However, for reasons set forth above the arguments are unpersuasive with respect to the 103 rejection.

#### ***Double Patenting***

15

Claims 1-7, 16-23, 28, 35 and 37 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-62 of U.S. Patent No. 6,464,848 B1 in view of Matsumoto (EP) and McCaffrey et al and Cozzette et al and Schillig et al.

20

It would have been obvious to provide the biosensor of the patent claims with an immobilized enzyme layer on the electrode between the electrode and protection layer (permeation-limiting layer) as suggested by Matsumoto disclosing an immobilized enzyme layer between an electrode and permeation-limiting layer. It would have been further obvious to provide between the immobilized enzyme layer and permeation-limiting layer an adhesion layer as suggested by McCaffrey

25

et al and Cozzette et al for reasons set forth above when applying these references to suggest an adhesion layer. Schillig et al would have suggested the permeation-limiting layer having grooves for reasons set forth above.

***Response to Arguments***

The amendment traverse this rejection based on reasons traversing the 103 rejection. However, for reasons set forth above the arguments are unpersuasive with respect to the 103 rejection.

***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David M. Naff

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whose telephone number is 571-272-0920. The examiner can normally be reached on Monday-Friday 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached on 571-272-0925.

5 The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained  
10 from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-  
15 9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



David M. Naff  
Primary Examiner  
Art Unit 1657